

657—20.15 (124,126,155A) Compounding for office use.

20.15(1) *Human compounded preparations.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if compounded by an Iowa-licensed pharmacy and sold directly to the practitioner by the compounding pharmacy.

20.15(3) *Office administration.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to an individual patient in the practitioner's office. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or to patients for administration outside of the office.

20.15(4) *Labeling.* Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

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